SECTION 5 - 510(k) Summary

MAR 2 7 2013

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

The assigned 510(k) number is: K121823

Submitter ELITechGroup Wescor ("Wescor")
Address 370 W 1700 S, Logan, UT 84321 USA
Phone number 435-752-6011
Fax number 435-752-4127

Contact Dawn T. Perdue (Email: d.perdue@elitechgroup.com)
Alternat Contact Dennis Briscoe, (d.briscoe@elitechgroup.com

Date of Preparation Thursday, March 21, 2013

Device name:

Trade/proprietary Name: **ChloroChek Chloridometer test system (containing;)**
CHLOROCHEK™ Chloridometer®[1]
CHLOROCHEK™ Reagent Set

Common or Usual Name: Clinical chloride analyzer, Chloride test system, Sweat Chloride Analyzer, Chloridometer ®, chloride coulometric

Regulatory:

Regulation	*Name*	*Classification*	*Product Code*	*Panel*
21 § 862.1170	Chloride test system	II	JFS	(75) Chemistry
21 § 862.1660	Quality Control	I, reserved	JJX	(75) Chemistry

Establishment Information:

The establishment registration number for ELITechGroup Wescor USA is 1717966.
The owner operator number for ELITechGroup North America (Wescor, Logan, UT, USA) is 1717966.

[1] "ChloroChek" is a registered trademark of Wescor Inc. "Chloridometer" is a registered trademark of LABCONCO that has been licensed exclusively to Wescor.

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Predicate device:

Predicate Instrument	*510(k) Number*
Buchler Instruments (Labconco), Chloridometer®.	K760394

Substantial Equivalence:

The Wescor CHLOROCHEK™ Chloridometer® test system (Model 3400 with associated reagent set (SS-248), is an *in vitro* diagnostic device which has been developed by Gonotec in Germany and is currently being OEM by. ELITechGroup Wescor. It has been demonstrated that the CHLOROCHEK™ Chloridometer® test system is substantially equivalent to the predicate device Buchler Instruments, Chloridometer® (now owned by Labconco) cleared under K760394.

Wescor ChloroChek ™ Reagent Set (SS-248) contains (a) ChloroChek™ Acid Buffer solution, a stabilizer (SS-248ABS), (b) ChloroChek™ Gelatin solution (SS-248GS), and (c) Wescor Standard solution 100mmol/L NaCl/H2O, (SS-251) which is used during the conditioning phase.

Device description:

The CHLOROCHEK™ Chloridometer® test system includes the Chloro-Chek Chloridometer analyzer and the ChloroChek Reagent Set. The system is for *in-vitro* diagnostics intended to measure the level of chloride in human sweat. It is a bench top chloride titrator for laboratory determinations of chloride concentrations.

Performance Standards:

To date, no performance standards that affect this device have been finalized under Section 514 of the Act.

Intended Use:

See Indications for Use

Indications for Use:

The Wescor ChloroChek Chloridometer test system is intended for the quantitative in vitro diagnostic determination of chloride in human sweat using the principle of coulometric titration. Sweat chloride measurements are used in the diagnosis of Cystic Fibrosis. It is for use in Clinical Laboratory settings. The Wescor Chloro-Chek Chloridometer test system consists of the ChloroChek Chloridometer and the ChloroChek Reagent Set.

The ChloroChek Reagent Set (SS-248), is to be used on the ChloroChek. It is used as the titration matrix during the titration process.

The 100 mmol/L $NaCl/H_2O$ Standard Solution (SS-251), is to be used on the ChloroChek. It is used as a calibration verifier, and quality control solution.

The Wescor Sweat Controls (SS-150), levels #1, #2, and #3, are to be used on the ChloroChek. They are used as quality control solutions.

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Comparison to Predicate device:

Difference		
	Wescor CHLOROCHEK™ Chloridometer® test system	Predicate device Buchler Instruments, (Labconco) Digital Chloridometer®
Sample Type	Samples of human sweat	Manual lists sweat, serum, plasma, and urine.
Sample Size	10 uL	10 uL on LOW range setting 100 uL on HIGH range setting
On board stability	No on board storage. Working solution in open container replaced each session at least daily.	No on board storage. Working solution good for eight hours at room temperature.
Calibration of instrument Frequency	Factory calibrated. Calibration is not required by the user. Return the instrument for service if the following occurs: 1) Not able to condition even after electrodes have been cleaned and or replaced. 2) Correct quality control values while using Sweat Control Solutions (SS-150) are not achieved. Conditioning and control steps are performed whenever the WORKING SOLUTION is replaced and thus 24hrs. See manual for specific procedure.	Factory calibrated and users can adjust if error exceeds specifications. Conditioning and control is conducted each day.
Method comparison	y=.9992x + 0.8754 r^2= 0.9886 range tested (non-spiked and spiked): 8.0 to 642 U/L	y=0.99x +1.01 U/L r^2= 0.9966 range: 3.70 to 671.80 U/L

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Similarities		
	Wescor CHLOROCHEK™ Chloridometer® test system	Predicate device Buchler Instruments, (Labconco) Digital Chloridometer®
Intended use/Indications for Use	The Wescor ChloroChek Chloridometer test system is intended for the quantitative in vitro diagnostic determination of chloride in human sweat using the principle of coulometric titration. Sweat chloride measurements are used in the diagnosis of Cystic Fibrosis. It is for use in Clinical Laboratory settings. The Wescor ChloroChek Chloridometer test system consists of the ChloroChek Chloridometer and the ChloroChek Reagent Set. The ChloroChek Reagent Set (SS-248), is to be used on the ChloroChek. It is used as the titration matrix during the titration process. The 100 mmol/L $NaCl/H_2O$ Standard Solution (SS-251), is to be used on the ChloroChek. It is used as a calibration verifier, and quality control solution. The Wescor Sweat Controls (SS-150), levels #1, #2, and #3, are to be used on the Chloro-Chek. They are used as quality control solutions.	Same, (Manual also lists plasma, serum, and urine.)
Reagent storage	There is a ChloroChek™ Reagent Set which contains 1 bottle of ChloroChek™ Gelatin Solution and 37 flasks of ChloroChek™ Acid Buffer Solution. The 1 bottle of ChloroChek™ Gelatin Solution is dispensed equally into each of the 37 flasks of ChloroChek™ Acid Buffer Solution to make the WORKING SOLUTION. Storage of ChloroChek™ Gelatin Solution is at 50-77°F (10-25°C). The ChloroChek™ Gelatin Solution is stable until the expiry date stated on the label. Storage of the ChloroChek™ Acid Buffer Solution is 50-86°F (10-30°C). The Chloro-Chek™ Acid Buffer Solution is stable until the expiry date stated on the label. Storage of the WORKING SOLUTION is 50-77°F (10-25°C). The WORKING SOLUTION is stable for 24 hours once prepared and must be prepared each day before use with the ChloroChek™.	Similar There are two solutions supplied with their instrument. One is a single bottle of Chloridometer™ Acid Reagent, which is a complete reagent solution to which the sample is added for titration. Storage of this Chloridometer Acid Reagent is at room temperature, with an expiry date that is printed on the bottle label, The second solution supplied is a Gelatin Reagent which is combined with an Acid solution and can be used as a substitute for the Acid Reagent. The Gelatin Reagent is stored at room temperature and expiration date is printed on the bottle. The combined Gelatin Reagent plus the prepared acid solution can be stored under refrigeration for up to six (6) months or kept at room temperature for eight (8) hours.

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	Similarities	
	Wescor CHLOROCHEK™ Chloridometer® test system	Predicate device Buchler Instruments, (Labconco) Digital Chloridometer®
Resolution	1 mmol/L over 20 second measurement duration	(Same) 1 mEq/L over a 20 second measurement duration
Solution appearance	Liquid, ready to use	Same
Expected values of Cl^-	Infant (0-6 months) Normal range ≤29 mmol/L Intermediate range 30-59 mmol/L Indicative of CF range ≥ 60 mmol/L Beyond Infancy (6 months-18 years) Normal range ≤39 mmol/L Intermediate range 40-59 mmol/L Indicative of CF range ≥ 60 mmol/L Adults (>18 years)* Normal range ≤39 mmol/L Intermediate range 40-59 mmol/L Indicative of CF range ≥ 60 mmol/L * *Exact ranges for adults are not fully defined.* See *CLSI C34-A3 for more information.*	Same
Measuring range	10 mmol/L to 160 mmol/L	Same
Precision	**Total** Low concentration (24mmol/L) CV=4.0% Medium concentration (49mmoll/L) CV=1.7% High concentration (100mmol/L) CV= 1.0% 100 mmol/L standard solution CV= 1.0% 10mmol/L standard solution CV= 5.6%	not specified

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	Similarities	
	Wescor CHLOROCHEK™ Chloridometer® test system	Predicate device Buchler Instruments, (Labconco) Digital Chloridometer®
Principle of operation	Coulometric titration	Same
Limitation	Halides (halogens) such as fluoride, bromide, or iodide will interfere and cause an elevated reading. CLSI acknowledges this in the C34-A3 guideline. "In addition to chloride, other halides such as bromide and iodide are also detected using a Chloridometer. Therefore, if a sweat sample contains other halides in addition to chloride, they will be detected and can falsely elevate the sweat chloride result." [(1)]. Halides may be present in lotions or creams, so it is important that the patients' skin is properly cleaned prior to collecting the sweat. Refer to the CLSI C34-A3 guidelines for cleaning the skin prior to pilocarpine iontophoresis.	Same

Conclusion:

A precision study was performed using two instruments, two lots of reagents, three operators, over 10 days on the three sweat levels, the 100mmol/L standard solution and a 10 mmol/L standard solution. The precision at the lower end of the measuring range, 10 mmol/L standard solution, was tested by 3 operators on 2 instruments with 2 reagent lots over 10 days and measured to be SD 0.6 mmol/L, 5.6% CV.

The linear range of the method (10-160 mmol/L) is compatible with the measurement of normal and pathological samples and the precision performance meets acceptance criteria. Likewise, correlation studies versus the predicate device meet acceptance criteria.

The data demonstrate the Wescor CHLOROCHEK™ Chloridometer® test system (analyzer (Model 3400 and associated ChloroChek Reagent Set (SS-248), [K121823], are substantially equivalent to the predicate device cleared under K760394.

The data demonstrate that the system is appropriate for its intended use and does not raise new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 27, 2013

Wescor, Inc.
c/o Dawn T. Perdue
370 West 1700 South
Logan, UT 84321

Re: k121823
Trade/Device Name: Wescor ChloroChek Chloridometer
Regulation Number: 21 CFR 862.1170
Regulation Name: Chloride Test System
Regulatory Class: II
Product Code: JFS, JJX
Dated: January 31, 2013
Received: February 14, 2013

Dear Ms. Perdue:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for

the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): k121823

Device Name: Wescor ChloroChek Chloridometer

Indication For Use:

The Wescor ChloroChek Chloridometer test system is intended for the quantitative in vitro diagnostic determination of chloride in human sweat using the principle of coulometric titration. Sweat chloride measurements are used in the diagnosis of Cystic Fibrosis. It is for use in Clinical Laboratory settings. The Wescor ChloroChek Chloridometer test system consists of the ChloroChek Chloridometer and the ChloroChek Reagent Set.

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Prescription Use ___X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Ruth A. Chesler -S

Division Sign-Off

Office of In Vitro Diagnostics and Radiological Health

510(k) k121823